MAY - 4 2005 K050561

4. Summary of Safety and Effectiveness

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter:
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Predicate Device(s)
Windsurfer is substantially equivalent to the VERICIS Physiolog (K013032).

Name of the Device:
Windsurfer

Description of the Device:
Windsurfer is a standard hemodynamic monitoring system for monitoring vital signs before, during and after catheterization procedures. Windsurfer is intended to acquire, display, store, analyze and process vital signs and log all cath lab activity. There are tools for entering measurements, calculations and procedure notes. Windsurfer also acquires patient information from other hospital information systems and makes hemodynamic information available to them.

Windsurfer is connected to a patient in the cath lab via:

- ECG leads
- Invasive Blood Pressure transducers
- SpO_2 finger clip
- NIBP cuff

Windsurfer uses an intuitive interface that clearly displays patient data, procedure data, waveforms and numeric values. The performing physician views the monitor in the cath lab and conveys instructions and procedure notes to the certified technician, who operates the application using a touch screen, keyboard and mouse, for maximum convenience.

February 27, 2005

Uzi Blumensohn — Date
Chief Executive Officer,
Medcon Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2005

Medcon, Ltd.
c/o Dr. Eli M. Orbach
International Regulatory Consultants
POB 6718
Efrat 90435
ISRAEL

Re: K050561
Trade Name: Windsurfer Hemodynamic Monitoring System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: February 27, 2005
Received: March 3, 2005

Dear Dr. Orbach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Zuckerman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050561

Device Name: Windsurfer

Indications For Use:

The Windsurfer is a system for acquiring, digitizing, storing, displaying and reviewing hemodynamic data (vital signs). The Windsurfer is intended for use in hospital cardiac catheterization laboratories.

Prescription Use ___Yes___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Welmes

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K050561

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Telemedicine Technology